

WHI Ancillary Study

SAMPLE

Fred Hutch WHI Clinical Coordinating Center Subcontract - Budget Justification

Budget Assumptions:

- 2,500 Plasma EDTA
- 2,500 Buffy Coat (needing full extraction)
- Half of specimen shipped to the testing lab in year 1, half in year 2.
- Three year study
- *Note that additional costs are incurred for plating samples, pooling samples, replacements for QNS, multiple aliquots, and specialized sort orders or batching. Also note this budget does not include effort for statistical analysis.*

Personnel:

Consortium PI

Calendar Months, Years 1-3: 0.60, 0.60, 0.60

% FTE, Years 1-3: 5.0%, 5.0%, 5.0%

The PI will maintain communication between the CCC and the investigators of this ancillary study, provide scientific expertise, assist with facilitating the WHI ancillary study process, and assist with data reporting, data analysis and manuscript preparation as appropriate.

Statistical Research Associate (SRA)

Calendar Months, Years 1-3: 0.48, 0.48, 0.24

% FTE, Years 1-3: 4.0%, 4.0%, 2.0%

The SRA will conduct case selection and prepare a datafile with common IDs to allow study Investigators to merge study lab data to existing covariate data. She/he will provide data file support as needed.

Systems Analyst/Programmer

Calendar Months, Years 1-3: 0.12, 0.12

% FTE, Years 1-3: 1.0%, 1.0%, 0.0%

The Programmer will coordinate the implementation and execution of the blood pull and subsequent receipt of results with appropriate CCC programming staff.

Study Coordinator

Calendar Months, Years 1-3: 0.48, 0.48, 0.12

% FTE, Years 1-3: 4.0%, 4.0%, 1.0%

The Study Coordinator will be responsible for the coordination of efforts between the CCC, Fisher BioServices, the Specimen Processing Lab (SPL), the Song Lab (QC), and the testing lab. She/he will coordinate the technical aspects of pulling and aliquoting blood samples, and oversee issues of sample selection, sample availability, and quality control. She/he will also prepare technical documentation and reports, and receive lab results.

Project Coordinator

Calendar Months, Years 1-3: 0.24, 0.24, 0.24

% FTE, Years 1-3: 2.0%, 2.0%, 2.0%

The Project Coordinator will be responsible for handling project-specific research support activities. She/he will coordinate CCC activities, monitor budgets and expenditures, submit IRB reports, and will be responsible for all the budgetary and administrative components of the WHI-CCC subcontract.

Inflation Rate

3%

Fringe Benefit Rates

Faculty	Staff
2015-2016 – 26.5%	2015-2016 – 34.5%
2016-2017 – 27%	2016-2017 – 35%
2017-2018 – 27.5%	2017-2018 – 35.5%

(Fringe benefits include FICA, medical and dental insurance, disability insurance, workmen's compensation, term life insurance, retirement, and state unemployment insurance. Holiday, sick leave, and other paid absences are considered a salary expense)

Purchased Services

	Year 1	Year 2	Total
EDTA	1,250.00	1,250.00	2,500.00
QC	<u>126.00</u>	<u>126.00</u>	<u>252.00</u>
TOTAL	1,376.00	1,376.00	2,752.00
Buffy	1,250.00	1,250.00	2,500.00
QC	<u>64.00</u>	<u>64.00</u>	<u>128.00</u>
TOTAL	1,314.00	1,314.00	2,628.00

Fisher BioServices

Fisher will be charged with the responsibility of pulling the 2,752 (2,500 cases and controls, 252 QC) identified Plasma EDTA aliquots and sending the aliquots on dry ice to the Specimen Processing Laboratory (SPL) during years one and two of the project. Fisher will process returned Plasma EDTA aliquots, receiving back and storing up to six samples per participant. Fisher will also pull 2,628 frozen buffy coat aliquots (2,500 cases and controls, and 128 QC) and send to SPL during years one and two of the project. Fisher will process returned DNA samples, receiving back and storing up to 2 samples per participant.

Year 1

<i>EDTA (Half of 2,500 samples, plus 10% QC)</i>	#	Unit cost	
Pulling and shipping	1,376	\$2.00	\$2,752.00
Receiving returned aliquots (6 /sample)	8,256	\$0.200	<u>\$1,651.20</u>
			\$4,403.20
<i>Buffy Coat (Half of 2,500 samples, plus 5% QC)</i>	#	Unit cost	
Pulling and shipping	1,314	\$2.00	\$2,628.00
Receiving returned aliquots (2 /sample)	2,628	\$0.200	<u>\$525.60</u>
			\$3,153.60
Year 1 TOTAL			\$7,557.00

Year 2

<i>EDTA (Half of 2,500 samples, plus 10% QC)</i>	#	Unit cost	
Pulling and shipping	1,376	\$2.06	\$2,834.56
Receiving returned aliquots (6 /sample)	8,256	\$0.206	<u>\$1,700.74</u>
			\$4,535.30

<i>Buffy Coat (Half of 2,500 samples, plus 5% QC)</i>	#	Unit cost	
Pulling and shipping	1,314	\$2.06	\$2,706.84
Receiving returned aliquots (2 /sample)	2,628	\$0.206	<u>\$541.37</u>
			\$3,248.21

Year 2 TOTAL **\$7,784.00**

Total Fisher BioServices **\$15,341.00**

Specimen Processing Lab (SPL) at Fred Hutchinson Cancer Research Center

The responsibility of the Specimen Processing Lab will be to aliquot Plasma EDTA samples into one .25 ml aliquot to be sent to the testing lab, and up to 6 daughter .25 ml aliquots to be sent to Fisher Repository for long-term storage. A total of 2,752 samples will be delivered in years 1 and 2 each. They will also extract DNA from each buffy coat sample and aliquot into one 0.5 µg daughter aliquot and two parent aliquots. They will ship the 0.5 µg DNA daughter aliquots on dry ice to the testing lab, and ship the remaining parent aliquots on dry ice back to Fisher for long-term storage. A total of 2,628 samples will be extracted and aliquoted and delivered in Years 1 and 2.

Year 1

<i>EDTA (Half of 2,500 samples, plus 10% QC)</i>	#	Unit cost	
Aliquoting	1,376	\$6.00	\$8,256.00
Shipping expenses (ice, boxes, shipping)	1,376	\$1.00	<u>\$1,376.00</u>
			\$9,632.00

<i>Buffy Coat (Half of 2,500 samples, plus 5% QC)</i>	#	Unit cost	
Extraction and aliquoting	1,314	\$29.00	\$38,106.00
Shipping expenses (ice, boxes, shipping)	1,314	\$1.00	<u>\$1,314.00</u>
			\$39,420.00

Year 1 total **\$49,052.00**

Year 2

<i>EDTA (Half of 2,500 samples, plus 10% QC)</i>	#	Unit cost	
Aliquoting	1,376	\$6.18	\$8,503.68
Shipping expenses (ice, boxes, shipping)	1,376	\$1.03	<u>\$1,417.28</u>
			\$9,920.96

<i>Buffy Coat (Half of 2,500 samples, plus 5% QC)</i>	#	Unit cost	
Aliquoting	1,314	\$29.87	\$39,249.18
Shipping expenses (ice, boxes, shipping)	1,314	\$1.03	<u>\$1,353.42</u>
			\$40,602.60

Year 2 Total **\$40,603.00**

SPL total **\$89,655.00**

Collaborative Data Services (CDS) at Fred Hutchinson Cancer Research Center

Collaborative Data Services will provide the printed labels for all specimen vials.

Year 1

	#	Unit Cost	
<i>EDTA Samples</i>			
7 labels per sample	9,632	\$0.12	<u>\$1,155.84</u>
			\$1,155.84

	#	Unit Cost	
<i>Buffy Coat Samples</i>			
5 labels per sample	6,570	\$0.12	\$788.40

TOTAL YEAR 1			\$1,944.00
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Year 2

	#	Unit Cost	
<i>EDTA Samples</i>			
7 labels per sample	9,632	\$0.1236	\$1,190.52

	#	Unit Cost	
<i>Buffy Samples</i>			
5 labels per sample	6,570	\$0.1236	\$812.05

TOTAL YEAR 2			\$2,003.00
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Total CDS			\$3,947.00
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Indirect Cost Rate

Calculated at 76% of Modified Direct Costs; rate effective as of February 20, 2014.